

Notice of Allowability

Application No.

10/066,419

Examiner

Scott M. Getzow

Applicant(s)

KROLL, MARK W.

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment submitted 8/23/04.
2. ☒ The allowed claim(s) is/are 1-10 and 12-33.
3. ☒ The drawings filed on 1/30/02 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

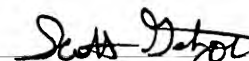
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Scott M. Getzow
Primary Examiner
Art Unit: 3762

PATENT

AMENDMENTS TO THE CLAIMS

Following is a complete set of claims as amended with this Response. This complete set of claims excludes cancelled claim 11 and includes amended claims 12 and 33.

1. (Original) An implantable cardiac device adapted to be implanted in pediatric patients, the device comprising:
 - at least one lead that is positionable adjacent a heart of the pediatric patient so as to be able to deliver pacing pulses thereto;
 - a pulse generator that produces pacing pulses and provides the pacing pulses to the at least one lead; and
 - a controller that controls the pulse generator to produce the pacing pulses, wherein the controller is configured to induce the delivery of pacing pulses to the heart at least at a basic pacing rate in the absence of any intrinsic heart activity, wherein the controller is further configured to adjust the basic pacing rate over time such that the basic pacing rate corresponds to an age related variation in an intrinsic heart rate of a normal child of a same age as the pediatric patient.
2. (Original) The device of Claim 1, further comprising a sensor that detects when the heart is providing an intrinsic heartbeat and provides a signal indicative thereof, wherein the controller receives the signal and inhibits delivery of pacing pulses when intrinsic heartbeats occur.
3. (Original) The device of Claim 1, further comprising a metabolic need sensor that provides signals to the controller indicative of the metabolic need of the pediatric patient, wherein the controller induces the delivery of pacing pulses at an adjusted pacing rate greater than the basic pacing rate to accommodate the sensed metabolic need of the pediatric patient.

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4. (Original) The device of Claim 1, wherein the controller adjusts the basic pacing rate during a first time interval wherein the intrinsic heart rate of a normal child is increasing and wherein the controller maintains a substantially constant basic pacing rate during a second time interval wherein the intrinsic heart rate of a normal child is substantially constant and wherein the controller decreases the basic pacing rate during a third time interval wherein the intrinsic heart rate of a normal child is decreasing.

5. (Original) The device of Claim 4, wherein the first interval comprises from the birth of the child until the child is approximately 14 days and wherein the controller adjusts the basic pacing rate from approximately 120 bpm to approximately 150 bpm.

6. (Original) The device of Claim 5, wherein the second interval comprises from 14 days until approximately 60-80 days and wherein the controller maintains the basic pacing rate at approximately 150 bpm.

7. (Original) The device of Claim 6, wherein the third interval comprises from approximately 75 days to 1000-1200 days and wherein the controller decreases the basic pacing rate from approximately 150 bpm to approximately 80 bpm.

8. (Original) The device of Claim 4, wherein the controller monitors a timer and periodically adjusts the basic pacing rate in response to the timer.

9. (Original) The device of Claim 4, wherein the controller monitors a body parameter of the pediatric patient that is indicative of age and adjusts the rate at least in part in response to the monitored body parameter.

10. (Original) The device of Claim 9, further comprising a transthoracic impedance sensor that provides signals to the controller that allows the controller to determine a respiration rate and wherein the controller evaluates the respiration rate to determine the age of the pediatric patient.

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11. (Cancelled)

12. (Currently Amended) The device of Claim 11, A pediatric pacemaker device that is capable of being implanted in a pediatric patient, the device comprising:
a pacing pulse delivery system that is adapted to generate and deliver pacing pulses to the patient; and
a controller that induces the delivery of pacing pulses to the pediatric patient, wherein the controller induces the delivery of pacing pulses at an adjustable pacing rate;
wherein the adjustable pacing rate is automatically adjusted over time based on the age of the patient; and

wherein the controller induces the delivery of pacing pulses to the patient at least at a basic pacing rate, in the absence of intrinsic heart activity and wherein the controller adjusts the basic pacing rate over time such that the basic pacing rate adjusts to correspond to the typical variation in intrinsic heart rates of a normal child of the same age as the pediatric patient.

13. (Original) The device of Claim 12, further comprising a sensor that detects when the heart is providing an intrinsic heartbeat and provides a signal indicative thereof, wherein the controller receives the signal and inhibits delivery of pacing pulses when intrinsic heartbeats occur.

14. (Original) The device of Claim 12, further comprising a metabolic need sensor that provides signals to the controller indicative of the metabolic need of the pediatric patient, wherein the controller induces the delivery of pacing pulses at an adjusted pacing rate greater than the basic pacing rate to accommodate the sensed metabolic need of the pediatric patient.

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15. (Original) The device of Claim 12, wherein the controller adjusts the basic pacing rate during a first time interval wherein the intrinsic heart rate of a normal child is increasing and wherein the controller maintains a substantially constant basic pacing rate during a second time interval wherein the intrinsic heart rate of a normal child is substantially constant and wherein the controller decreases the basic pacing rate during a third time interval wherein the intrinsic heart rate of a normal child is decreasing.

16. (Original) The device of Claim 15, wherein the first interval comprises from the birth of the child until the child is approximately 14 days and wherein the controller adjusts the basic pacing rate from approximately 120 bpm to approximately 150 bpm.

17. (Original) The device of Claim 16, wherein the second interval comprises from 14 days until approximately 60-80 days and wherein the controller maintains the basic pacing rate at approximately 150 bpm.

18. (Original) The device of Claim 17, wherein the third interval comprises from approximately 75 days to 1000-1200 days and wherein the controller decreases the basic pacing rate from approximately 150 bpm to approximately 80 bpm.

19. (Original) The device of Claim 15, wherein the controller monitors a timer and periodically adjusts the basic pacing rate in response to the timer.

20. (Original) The device of Claim 15, wherein the controller monitors a body parameter of the pediatric patient that is indicative of age and adjusts the rate at least in part in response to the monitored body parameter.

21. (Original) The device of Claim 20, further comprising a transthoracic impedance sensor that provides signals to the controller that allows the controller to determine a respiration rate and wherein the controller evaluates the respiration rate to determine the age of the pediatric patient.

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22. (Original) An implantable cardiac stimulation device, adapted to be implanted in a pediatric patient, the device comprising:
means for generating pacing pulses to be delivered to a heart of the pediatric patient; and
control means for controlling the delivery of pacing pulses to the heart of the pediatric patient, wherein the control means induces the delivery of pacing pulses at an adjustable rate wherein the rate is adjusted based on the age of the pediatric patient so that the pediatric patient has a heart rate that varies to correspond with age-based variations in an intrinsic heart rate of a normal child.
23. (Original) The device of Claim 22, wherein the control means induces the delivery of pacing pulses to the patient at least at a basic pacing rate, in the absence of intrinsic heart activity and wherein the control means adjusts the basic pacing rate over time such that the basic pacing rate adjusts to correspond to the typical variation in intrinsic heart rates of a normal child of the same age as the pediatric patient.
24. (Original) The device of Claim 23, further comprising a sensor that detects when the heart is providing an intrinsic heartbeat and provides a signal indicative thereof, wherein the control means receives the signal and inhibits delivery of pacing pulses when intrinsic heartbeats occur.
25. (Original) The device of Claim 24, further comprising a metabolic need sensor that provides signals to the control means indicative of the metabolic need of the pediatric patient, wherein the control means induces the delivery of pacing pulses at an adjusted pacing rate greater than the basic pacing rate to accommodate the sensed metabolic need of the pediatric patient.

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26. (Original) The device of Claim 23, wherein the control means adjusts the basic pacing rate during a first time interval wherein the intrinsic heart rate of a normal child is increasing and wherein the control means maintains a substantially constant basic pacing rate during a second time interval wherein the intrinsic heart rate of a normal child is substantially constant and wherein the control means decreases the basic pacing rate during a third time interval wherein the intrinsic heart rate of a normal child is decreasing.

27. (Original) The device of Claim 26, wherein the first interval comprises from the birth of the child until the child is approximately 14 days and wherein the control means adjusts the basic pacing rate from approximately 120 bpm to approximately 150 bpm.

28. (Original) The device of Claim 27, wherein the second interval comprises from 14 days until approximately 60-80 days and wherein the control means maintains the basic pacing rate at approximately 150 bpm.

29. (Original) The device of Claim 28, wherein the third interval comprises from approximately 75 days to 1000-1200 days and wherein the control means decreases the basic pacing rate from approximately 150 bpm to approximately 80 bpm.

30. (Original) The device of Claim 23, wherein the control means monitors a timer and periodically adjusts the basic pacing rate in response to the timer.

31. (Original) The device of Claim 23, wherein the control means monitors a body parameter of the pediatric patient that is indicative of age and adjusts the rate at least in part in response to the monitored body parameter.

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32. (Original) The device of Claim 31, further comprising a transthoracic impedance sensor that provides signals to the controller that allows the control means to determine a respiration rate and wherein the control means evaluates the respiration rate to determine the age of the pediatric patient.

33. (Currently Amended) In an implantable cardiac stimulation device, a method of pacing a heart of a pediatric patient, the method comprising:
setting a pacing rate based on the age of the pediatric patient; and
on at least one subsequent occasion, automatically adjusting the pacing rate based on an updated age of the pediatric patient so that the pediatric patient has a heart rate that varies to correspond with age-based variations in an intrinsic heart rate of a normal child.